# INTERSPINOUS PROCESS IMPLANT WITH RADIOLUCENT SPACER AND LEAD-IN TISSUE EXPANDER


INVENTORS:

James F. Zucherman
Ken Y. Hsu
Charles J. Winslow
John Flynn
Steve Mitchell



**CERTIFICATE OF MAILING BY "EXPRESS MAIL" UNDER 37 C.F.R. §1.10**

**"Express Mail" mailing label number: EV326481909 US**
**Date of Mailing:** 10/27/03

I hereby certify that this correspondence is being deposited with the United States Postal Service, utilizing the "Express Mail Post Office to Addressee" service addressed to: **MAIL STOP PATENT APPLICATION, COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450** and mailed on the above Date of Mailing with the above "Express Mail" mailing label number.

Tina M. Galdos (Signature)
Name: Tina Galdos
Signature Date: 10/27/03

# INTERSPINOUS PROCESS IMPLANT WITH RADIOLUCENT SPACER AND LEAD-IN TISSUE EXPANDER

**Inventors:**

**James F. Zucherman**
**Ken Y. Hsu**
**Charles J. Winslow**
**John Flynn**
**Steve Mitchell**

## CLAIM TO PRIORITY

[0001] This application claims priority to U.S. Provisional Application No. 60/421,915, filed October 29, 2002, entitled "INTERSPINOUS PROCESS IMPLANT WITH RADIOLUCENT SPACER AND LEAD-IN TISSUE EXPANDER," which is incorporated herein by reference.

## CROSS-REFERENCE TO RELATED APPLICATIONS

This application is related to U.S. Patent Application No. 10/230,505, filed August 29, 2002, entitled "DEFLECTABLE SPACER FOR USE AS AN INTERSPINOUS PROCESS IMPLANT AND METHOD," U.S. Provisional Application No. 60/421,921, filed October 29, 2002, entitled "INTERSPINOUS PROCESS APPARATUS AND METHOD WITH A SELECTABLY EXPANDABLE SPACER," and U.S. Patent Application No. 10/___,___, filed October 14, 2003, entitled "INTERSPINOUS PROCESS APPARATUS AND METHOD FOR SELECTABLY EXPANDABLE SPACER," which are incorporated herein by reference. This application is also related to U.S. Patent Application No. 10/037,236, filed November 9, 2001, which is related to U.S. Patent Application No. 09/799,215, filed March 5, 2001, which is related to U.S. Patent Application No. 09/473,173, filed December 28, 1999, now U.S. Patent No. 6,235,030, which is related to U.S. Patent Application No. 09/179,570, filed October 27, 1998, now U.S. Patent No. 6,048,342, which is related to U.S. Patent Application No. 09/474,037, filed

December 28, 1999, now U.S. Patent No. 6,190,387, which is related to U.S. Patent Application No. 09/175,645, filed October 20, 1998, now U.S. Patent 6,068,630. All of the above are incorporated herein by reference.

## FIELD OF THE INVENTION

**[0002]** This invention relates to an interspinous process implant.

## BACKGROUND OF THE INVENTION

**[0003]** The spinal column is a bio-mechanical structure composed primarily of ligaments, muscles, vertebrae and intervertebral disks. The bio-mechanical functions of the spine include: (1) support of the body, which involves the transfer of the weight and the bending movements of the head, trunk and arms to the pelvis and legs, (2) complex physiological motion between these parts, and (3) protection of the spinal cord and the nerve roots.

**[0004]** As the present society ages, it is anticipated that there will be an increase in adverse spinal conditions which are characteristic of older people. By way of example, with aging comes an increase in spinal stenosis (including, but not limited to, central canal and lateral stenosis), and facet arthropathy. Spinal stenosis typically results from the thickening of the bones that make up the spinal column and is characterized by a reduction in the available space for the passage of blood vessels and nerves. Pain associated with such stenosis can be relieved by medication and/or surgery. Of course, it is desirable to eliminate the need for major surgery for all individuals, and, in particular, for the elderly.

**[0005]** In addition, there are a variety of other ailments that can cause back pain in patients of all ages. For these ailments it is also desirable to eliminate such pain without major surgery.

[0006] Accordingly, there needs to be developed implants for alleviating such conditions which are minimally invasive, can be tolerated by patients of all ages, and, in particular, the elderly, and can be performed preferably on an out patient basis.

## SUMMARY OF THE INVENTION

[0007] The present invention is directed to providing a minimally invasive implant for alleviating discomfort associated with the spinal column. The implant is characterized in one embodiment in that the spacer and the lead-in tissue expander or distraction guide are comprised of a material that is radiolucent. In another embodiment, the spacer can be deflectable. Suitable materials include, for example, polyetheretherketone (PEEK) and polyetherketoneketone (PEKK). Other material that can be used include polyetherketone (PEK), polyetherketoneetherketoneketone (PEKEKK), and polyetheretherketoneketone (PEEKK), and, generally, a polyaryletheretherketone. Further, other polyketones can be used as well as other thermoplastics. Such materials are advantageously radio-translucent, radiolucent or transparent to x-rays or other imaging techniques. Additional suitable materials can be selected from the groups including by way of example, high molecular weight polymers, and thermoplastics. Thus, the radiolucent nature of the spacer and distraction guide enables the implant to retain a high degree of structural support after being implanted while not impairing the ability to view the patient's anatomy in a subsequent x-ray. Other aspects, objects, features and elements of embodiments of the invention are described or evident from the accompanying specification, claims and figures.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0008] **FIGS. 1A-1F**. **FIG. 1A** is a front plan view of an embodiment of an assembled implant of the invention; **FIG. 1B** is a left side view of the embodiment of the invention of **FIG. 1A**; **FIG. 1C** is a front plan view of the embodiment of the

invention of **FIG. 1A** including a spacer, a main body and a first wing; **FIG. 1D** is a left side view of the second wing of the embodiment of the invention of **FIG. 1A**; **FIG. 1E** is a front plan view of the second wing of the embodiment of the invention of **FIG. 1A**; **FIG. 1F** is an end view of the spacer of the embodiment of the invention of **FIG. 1A**.

[0009] **FIG. 2A** is a perspective view of an embodiment of the frame of the tissue expander or distraction guide of the invention. **FIG. 2B** is a perspective view of an embodiment of the lead-in tissue expander or distraction guide of the invention.

[0010] **FIGS. 3A** and **3B** are an end and a perspective view of still another embodiment of the spacer of the invention. **FIG. 3C** is a front view of the spacer of **FIG. 3A**.

[0011] **FIGS. 4A** and **4B** are an end and a perspective view of yet another embodiment of the spacer of the invention.

[0012] **FIGS. 5A** and **5B** are an end and a perspective view of still another embodiment of the spacer of the invention.

[0013] **FIGS. 6A** and **6B** are an end and a perspective view of a further embodiment of the spacer of the invention.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS OF THE INVENTION

[0014] The following description is presented to enable any person skilled in the art to make and use the invention. Various modifications to the embodiments described will be readily apparent to those skilled in the art, and the principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present invention as defined by the appended claims. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein. To the extent necessary to achieve a complete understanding of the invention disclosed, the specification and

drawings of all patents and patent applications cited in this application are incorporated herein by reference

[0015] An embodiment of an implant ***100*** of the invention is depicted in **FIG. 1A.** This implant ***100*** includes a first wing ***104*** and a spacer ***150*** and a lead-in tissue expander or distraction guide ***110***. This embodiment further can include, as required, a second wing ***132.*** As can be seen in **FIG. 1A**, a shaft ***102*** extends from the first wing ***104*** and is the body that connects the first wing ***104*** to the tissue expander or distraction guide ***110***. Also, as can be seen in **FIGS. 1A** and **1B**, the distraction guide ***110*** in this particular embodiment acts to distract the soft tissue and the spinous processes when the implant ***100*** is inserted between adjacent spinous processes. In this particular embodiment, the guide ***110*** has an expanding cross-section from the distal end ***111*** to the area where the second wing ***132*** is secured to the guide ***110***. In this embodiment the guide ***110*** is wedge-shaped.

[0016] Additionally, as can be seen in **FIGS. 1A** and **1F**, the spacer ***150*** is elliptical-shaped in cross-section. The spacer ***150*** can have other shapes such as circular, oval, ovoid, football-shaped, and rectangular-shaped with rounded corners and other shapes, and be within the spirit and scope of the invention. In this preferred embodiment, the spacer ***150*** includes a bore ***152*** which extends the length of the spacer ***150***. The spacer ***150*** is received over the shaft ***102*** of the implant ***100*** and can rotate thereon about the shaft ***102***. In these embodiments, the spacer ***150*** can have minor and major dimensions as follows:

| Minor Dimension (116a) | Major Dimension (116 b) |
|---|---|
| 6 mm | 13.7 mm |
| 8 mm | 14.2 mm |
| 10 mm | 15.2 mm |
| 12 mm | 16.3 mm |
| 14 mm | 17.8 mm |

[0017] The advantage of the use of the spacer ***150*** as depicted in the embodiment of **FIG. 1A**, is that the spacer ***150*** can be rotated and repositioned with respect to the first wing ***104***, in order to more optimally position the implant ***100*** between spinous processes. It is to be understood that the cortical bone or the outer bone of the spinous processes is stronger at an anterior position adjacent to the vertebral bodies of the vertebra than at a posterior position distally located from the vertebral bodies. Also, biomechanically for load bearing, it is advantageous for the spacer ***150*** to be close to the vertebral bodies. In order to facilitate this and to accommodate the anatomical form of the bone structures, as the implant is inserted between the spinous processes and/or urged toward the vertebral bodies, the spacer ***150*** rotates relative to the wings, such as wing ***104***, so that the spacer ***150*** is optimally positioned between the spinous processes, and the wing ***104*** is optimally positioned relative to the spinous processes. Further, the broad upper and lower surfaces of the spacer ***150*** helps spread the load that the spinous processes place on the spacer ***150***.

[0018] As may be required for positioning the implant ***100*** between the spinous processes, the implant ***100*** can also include a second wing ***132*** which fits over the guide ***110*** and is secured by a bolt ***130*** placed through an aperture ***134*** provided in a tongue ***136*** of second wing ***132***. The bolt ***130*** is received and

secured in the threaded bore ***112*** located in the guide ***110***. As implanted, the first wing ***104*** is located adjacent to first sides of the spinous processes and the second wing ***132*** is located adjacent to second sides of the same spinous processes.

**[0019]** In another embodiment, the spacer ***150*** has a cross-section with a major dimension and a minor dimension, wherein the major dimension is greater than the minor dimension, and, for example, less than about two times the minor dimension. It is to be understood that the spacer ***150*** can be fabricated from somewhat flexible and/or deflectable material.

**[0020]** In this embodiment the spacer is made out of a polymer, more specifically, the polymer is a thermoplastic. Still more specifically, the polymer is a polyketone known as polyetheretherketone (PEEK). Still more specifically, the material is PEEK 450G, which is an unfilled PEEK approved for medical implantation available from Victrex of Lancashire, Great Britain. (Victrex is located at www.matweb.com or see Boedeker www.boedeker.com). Other sources of this material include Gharda located in Panoli, India (www.ghardapolymers.com). The spacer ***150*** can be formed by extrusion, injection, compression molding and/or machining techniques. This material has appropriate physical and mechanical properties and is suitable for carrying and spreading the physical load between the spinous process. Further in this embodiment, the PEEK has the following additional approximate properties:

| Property | Value |
|---|---|
| Density | 1.3 g/cc |
| Rockwell M | 99 |
| Rockwell R | 126 |
| Tensile Strength | 97 MPa |
| Modulus of Elasticity | 3.5 GPa |
| Flexural Modulus | 4.1 GPa |

[0021] In a preferred embodiment, the implant ***100*** is comprised in part of titanium or other suitable implant material which may be radiopaque and in part of a radiolucent material that does not show up under x-ray or other type of imaging. In a preferred embodiment, the first and second wings and the shaft are comprised of such a radiopaque material such as titanium and the spacer and the distraction guide or tissue expander are comprised of a radiolucent material such as, for example, PEEK or PEKK or other radiolucent materials described herein. In an embodiment which includes the first wing, the spacer and the tissue expander, under imaging, the implant looks like an "T". In an embodiment which includes both a first and a second wing, the spacer and the tissue expander, under imaging, the implant looks like a "H". This embodiment allows the doctor to have a clearer view of the spine under imaging without the implant interfering as much with the view of the bone structure.

[0022] It should be noted that the material selected may also be filled. For example, other grades of PEEK are also available and contemplated, such as 30% glass-filled or 30% carbon-filled, provided such materials are cleared for use in implantable devices by the FDA, or other regulatory body. Glass-filled PEEK reduces the expansion rate and increases the flexural modulus of PEEK relative to that which is unfilled. The resulting product is known to be ideal for improved

strength, stiffness, or stability. Carbon-filled PEEK is known to enhance the compressive strength and stiffness of PEEK and lower its expansion rate. Carbon-filled PEEK offers wear resistance and load carrying capability.

[0023] In this embodiment, as described above, the spacer ***150*** is manufactured from polyetheretherketone (PEEK), available from Victrex. As will be appreciated, other suitable similarly biocompatible thermoplastic or thermoplastic polycondensate materials that resist fatigue, have good memory, are flexible, and/or deflectable, have very low moisture absorption, and good wear and/or abrasion resistance, can be used without departing from the scope of the invention. The spacer can also be comprised of polyetherketoneketone (PEKK).

[0024] Other material that can be used include polyetherketone (PEK), polyetherketoneetherketoneketone (PEKEKK), and polyetheretherketoneketone (PEEKK), and generally a polyaryletheretherketone. Further, other polyketones can be used as well as other thermoplastics. The spacer can also be made of titanium.

[0025] Reference to appropriate polymers that can be used in the spacer can be made to the following documents, all of which are incorporated herein by reference. These documents include: PCT Publication WO 02/02158 A1, dated January 10, 2002, entitled "Bio-Compatible Polymeric Materials;" PCT Publication WO 02/00275 A1, dated January 3, 2002, entitled "Bio-Compatible Polymeric Materials;" and, PCT Publication WO 02/00270 A1, dated January 3, 2002, entitled "Bio-Compatible Polymeric Materials."

[0026] Other materials such as Bionate®, polycarbonate urethane, available from the Polymer Technology Group, Berkeley, California, may also be appropriate because of the good oxidative stability, biocompatibility, mechanical strength and abrasion resistance. Other thermoplastic materials and other high molecular weight polymers can be used.

[0027] **FIG. 2A** and **FIG. 2B** shown an embodiment of the distraction guide or tissue expander ***110***. **FIG. 2A** shows a frame ***200*** for a distraction guide ***110***. The

frame ***200*** is typically manufactured from radiopaque material such as titanium. The frame ***200*** has a first end ***202*** and a second end ***204***. The first end ***202*** has a shaft ***102*** which can be threaded with threads ***234*** at one end to facilitate connection to, for example, a first wing ***104***. The remaining end of the shaft connects to a distraction head frame ***230*** for the distraction guide ***110.*** Alternatively, the shaft ***102*** and the distraction head frame ***230*** can be formed integral to each other.

[0028] Further, the distraction head frame ***230***, the shaft ***102*** and the first wing ***104*** can be formed as one unit. Still further in an embodiment with a screw thread ***234*** formed at one end of the shaft ***102***, which thread ***234*** is received in a threaded bore of the first wing ***102***, the thread ***234*** can be laser welded into the threaded bore of the first wing ***102***, if desired.

[0029] The distraction head frame ***230*** is formed to take on a relatively low profile because, as described above, it is typically formed of radiopaque material. As shown in **FIG. 2A**, distraction head frame ***230*** has two pairs of parallel sides. The first pair of parallel sides ***210, 212*** extends into a pair of flanges ***232, 233*** that define a recess ***236.*** The second pair of parallel sides ***214, 216*** are perpendicular to the first pair of parallel sides. One of the second pair of parallel sides ***214*** abuts the shaft ***102***. As will be appreciated by those of skill in the art, neither the first or second pair of parallel sides need be parallel to each other, nor do the first pair of parallel sides need to be perpendicular to the second pair of parallel sides in order to practice the invention.

[0030] With respect to the frame ***200*** in **FIG. 2A**, the distraction head frame ***230*** has an upper surface ***218*** within the recess ***236*** with a threaded bore ***112*** therein. The threaded bore ***112*** receives, for example, a bolt ***130*** to secure the second wing ***132*** to the distraction guide ***110*** via the tongue ***136*** on the second wing ***132*** (shown in more detail with respect to **FIG. 1A**). The profile of the bolt ***130*** is such that the height of the bolt ***130*** and the tongue ***136*** fits within the recess ***236***.

[0031] The lower surface ***220*** opposing the upper surface ***218*** can have a first portion ***222*** that is parallel, or substantially parallel, to the upper surface ***218***. Additionally, a second portion ***224*** can be angled from the first portion ***222*** toward one of the second parallel sides ***216***. The angled configuration of the lower surface ***220*** is designed to facilitate the angled profile of the distraction guide.

[0032] **FIG. 2B** shows a perspective view of the distraction guide ***110***. The frame ***200,*** as described above, is manufactured from radiopaque material. A cap ***260*** is formed of radiolucent material, such as a suitable polymer, around the frame ***200***. Suitable polymers include, but are not limited to the polyketones discussed above with respect to the spacer configurations. Accordingly, for example, PEEK, PEKK, PEK, PEKEKK and PEEKK can be used as well as the other materials that are suitable for the spacer ***150***. As will be appreciated by those of skill in the art, the cap ***260*** can be associated with the frame ***200*** by a variety of techniques such that the cap ***260*** is formed to the frame ***200*** or is adhered to the frame ***200*** using a suitable method. As illustrated in **FIG. 2B**, the cap ***260*** has a higher profile than the frame ***200*** and is shaped to facilitate the second end ***204*** of the distraction guide ***110*** acting to expand tissue when the distraction guide is implanted between spinous processes or used to distract adjacent spinous processes.

[0033] Referring now to **FIGS. 3A-6B**, various embodiments of spacers are depicted. In **FIGS. 3A**, **3B** and **3C**, the spacer ***350*** includes an outer spacer ***352*** and an inner spacer ***354***. Inner spacer ***354*** has a bore ***360*** therethrough that enables the spacer ***350*** to rotate about the shaft ***102*** of implant ***100*** shown in **FIG. 1A.**

[0034] Each of the inner and outer spacers of the spacer ***350*** can have a cross-section that is elliptical, oval, ovoid, football-shaped, circular-shaped, rectangular with rounded ends (where the cross-section has two somewhat flattened surfaces and two rounded surfaces similar to the effect of a flattened ellipse). Further, the inner spacer and outer spacer can have different cross-sectional

shapes relative to each other. At least the minor outer diameter of the outer spacer is between 6 mm and 14 mm. Typically, the minor outer dimension is one of 6 mm, 8 mm, 10 mm, 12 mm, and 14 mm. The different sizes enable the spacer to accommodate different sized patients.

[0035] As depicted in **FIG. 3A**, the spacer ***350*** is a rectangle with rounded ends or a flattened ellipse, as it has two sides that are almost parallel to each other, and the ends connecting the parallel sides are curved, similar to a "race-track." Thus, in this and other embodiments, the two sides or surfaces of the spacer, including the upper and the lower spacer, can also be flattened or slightly radiused. The bore ***360*** is located in the center of the inner spacer ***354*** and there is a gap ***362*** between the upper and lower portions of the outer spacer ***352*** and the inner spacer ***354***. A gap ***370*** is provided between the inner and outer spacers at the rounded ends ***356***, ***358***. In a preferred embodiment, for about an 8 millimeter spacer ***350***, the upper and lower gaps ***362*** are about 0.012 of an inch or about a quarter of a millimeter each for a total combined gap of about one half of a millimeter. The gaps ***370*** at the curved ends ***356***, ***358*** are about 0.002 of an inch or slightly less than a tenth of a millimeter each in a preferred embodiment. The gap ***370*** for all of the other spacers is preferably, as specified above, for the 8mm spacer. For the 6 millimeter spacer, generally this is made of one piece such as seen in **FIG. 1F**. However, for the other spacers, these spacers are preferably made of two pieces as seen for example in **FIG. 3A**. The table below sets our preferred dimensions for the combined upper and lower gap dimension for the spacers.

| Spacer Minor Dimension | Total Combined Gap Dimension |
|---|---|
| 6 mm | n/a |
| 8 mm | 0.020 in (0.51 mm) |
| 10 mm | 0.025 in (0.64 mm) |
| 12 mm | 0.030 in (0.76 mm) |
| 14 mm | 0.035 in (0.89 mm) |

[0036] The gap ***362*** closed and the inner and outer spacers touch each other when the spacer is loaded with 800 newtons of force. The design is made to take repeated loading at 1200 newtons of force.

[0037] In the above embodiment, the outer spacer ***352*** is movably or slidably mounted on the inner spacer ***354***, and the inner spacer ***354*** is rotatably mounted on the shaft ***102*** of the implant ***100.***

[0038] As discussed above, the spacer, including either the inner spacer or outer spacer, or both, can be made of deflectable and flexible material. As discussed above, suitable material is a polymer such as for example polyetheretherketone (PEEK). Other suitable materials can include those described above. Further, titanium can be used.

[0039] Further, the deflectable or flexible material can have a graduated stiffness to help gradually distribute the load when the spinous processes place a force upon the exterior surface of the outer spacer ***352***. This can be accomplished by forming multiple layers of the deflectable or flexible material with decreasing stiffness or hardness from the center of the spacer ***350*** outwardly. Alternatively, the material can have a higher stiffness or hardness in the center of the inner spacer.

[0040] Persons of skill in the art will appreciate that the embodiments shown in **FIGS. 4A-6B**, can be made of the materials similar to those emphasized in the embodiment shown in **FIGS. 1A** and **3A**.

[0041] Now referring to **FIGS. 4A** and **4B**, again the spacer ***450*** is depicted as a somewhat flattened ellipse with rounded ends ***456, 458***, where two sides are somewhat parallel to each other and the ends connecting the parallel sides are curved, similar to a "race-track." The bore ***460*** is located off-center within the inner spacer ***454.*** Further, there are gaps ***462, 470*** between the outer spacer ***452*** and the inner spacer ***454***. Except for the location of the bore ***460***, the dimensions and materials of the embodiment of **FIGS. 4A** and **4B** are similar to that of **FIG. 3A** and **FIG. 3B**.

[0042] The off-center bore ***460*** allows a greater portion of the spacer ***450*** to be positioned close to the vertebral bodies. With an ovoid ("egg-shaped") spacer, off-set the bore ***460*** is preferably close to the bulbous end of the spacer with the more pointed end directed toward the vertebral bodies in order to attain the advantages of the spacer being closer to the vertebral bodies and enhanced distributed load bearing.

[0043] Turning now to **FIG. 5**, the spacer ***550*** is depicted as having a circular cross-section. The bore ***560*** is located within the inner spacer ***554.*** Further, there are gaps ***562***, ***570*** between the outer spacer ***552*** and the inner spacer ***554***. The dimensions of the gap would be the same as those discussed with respect to the embodiment shown in **FIG. 3A**. The embodiment of **FIG. 3A** can have a diameter that is the minor diameter of the embodiments shown in **FIGS. 1A**, **3A**, and **4A**.

[0044] Also, as will be appreciated by those in skill in the art, the outer spacer ***552*** can be movably mounted on the inner spacer ***554*** and the inner spacer ***554*** can be rotatably mounted on the shaft ***102*** of the implant ***100*** or any other suitable implant.

[0045] In **FIGS. 6A** and **6B**, the spacer ***650*** is depicted as having an outer spacer ***652*** and an inner spacer ***654*** of two different cross-sectional shapes. In this embodiment, the outer spacer ***652*** is elliptical and the inner spacer is football-shaped in cross-sections. The bore ***660*** is located off-center within the inner spacer ***654.*** However, as will be appreciated by those of skill in the art, the bore ***660*** can be located centrally within the inner spacer without departing from the scope of the invention.

[0046] The gaps ***662*** between the outer spacer ***652*** and the inner spacer ***654*** are crescent-shaped as a result of the inner and outer spacers having different cross-sectional shapes. Thus, the gap can have a width ranging from approximately between 0.25 mm at the minor diameter (greatest vertical height) to just enough space at the apexes ***662***, ***664*** of the inner spacer ***654*** so that the outer spacer can slide over the inner spacer. The inner spacer ***654*** can be rotatably mounted on the shaft ***102*** of the implant ***100.***

[0047] The embodiment of this implant as well as the several other implants described herein act to limit extension (backward bending) of the spine. These implants, however, do not inhibit the flexion (forward bending) of the spinal column.

[0048] The foregoing description of embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention and the various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims and its equivalence.